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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,573	05/25/2001	John S. Hauran	4305-1 J396-US1	4477

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DARBY & DARBY  
805 THIRD AVENUE, 27TH FLR.  
NEW YORK, NY 10022

EXAMINER

JAMROZ, MARGARET E

ART UNIT PAPER NUMBER

1644

DATE MAILED: 11/26/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/866,573

Applicant(s)

HAURUM ET AL.

Examiner

Margaret E Jamroz

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-24 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s) _____           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)         |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input checked="" type="checkbox"/> Other: <u>restriction election facsimile</u> |

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### DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz in Art Unit 1644, Technology Center 1600.

#### ***Restriction Requirement***

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2 and 5-14, drawn to a pharmaceutical composition comprising a recombinant polyclonal antibody; classified in Class 424, subclasses 133.1 and 171.1.

II. Claims 1, 3, 5-9, and 13-14, drawn to a pharmaceutical composition comprising a mixture of individual monoclonal antibodies; classified in Class 424, subclasses 141.1 and 171.1.

III. Claims 1, 4-9, and 13-14, drawn to a pharmaceutical composition comprising an isolated or purified polyclonal antibody; classified in Class 424, subclasses 130.1 and 171.1.

IV. Claims 15-18, and 21-22, drawn to the use of a recombinant polyclonal antibody for the manufacture of a pharmaceutical composition; classified in Class 424, subclasses 133.1 and 171.1.

V. Claims 15-17 and 19, drawn to the use of a mixture of individual monoclonal antibodies for the manufacture of a pharmaceutical composition; classified in Class 424, subclass 141.1.

VI. Claims 15-17 and 20, drawn to the use of an isolated or purified polyclonal antibody for the manufacture of a pharmaceutical composition; classified in Class 424, subclass 130.1.

VII. Claims 23-24, drawn to a method of preventing or treating allergy comprising administering a recombinant polyclonal antibody ; classified in Class 424, subclasses 133.1 and 171.1.

VIII. Claims 23-24, drawn to a method of preventing or treating allergy comprising administering an isolated or purified polyclonal antibody; classified in Class 424, subclasses 130.1 and 171.1.

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4. Groups I-III are different products. Recombinant polyclonal antibodies, monoclonal antibodies, and polyclonal polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

5. Groups IV-VIII are different methods. The inventions as grouped in Groups IV-VIII are distinct, each from the other, because they represent different inventive endeavors as one does not suggest the other; therefore, each method is patentably distinct.

<sup>IV</sup>  
Groups ~~VII~~ <sup>IV</sup> VIII recite method of preventing or treating allergy or making a composition with a recombinant polyclonal antibody, a mixture of individual monoclonal antibodies, or an isolated or purified polyclonal antibody. Methods utilizing a recombinant polyclonal antibody, a mixture of individual monoclonal antibodies, or an isolated or purified polyclonal antibody differ with respect to the structure of their ingredients; one of ordinary skill in the art would not envision one in view of the other; therefore, they are patentably distinct.

6. (Groups I and IV/VII), (Groups II and V), and (Groups III and VI/VIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the antibodies of groups I-III can be used in a materially different process, such as a affinity chromatography, in addition to the methods of treating recited.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

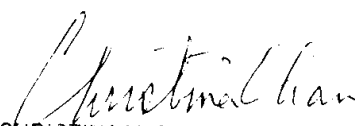
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 20, 2001

  
CHRISTINA Y. CHAN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800 1644